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101 Federal Street
Boston, MA 02110

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,124,316

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,124,316, which claims the medical device GEM 21S® Growth-Factor Enhanced Matrix, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 989 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 989 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of June 1, 2007 (72 Fed. Reg. 30598). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (744) + 617 \\ &= 989 \text{ days (2.7 years)}\end{aligned}$$

Since the regulatory review period began February 28, 2002, after the patent issued (June 23, 1992), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 5,124,316

Granted: June 23, 1992

Original Expiration Date¹: June 23, 2009

Applicant: Harry N Antoniades et al.

Owner of Record: President and Fellows of Harvard College and BioMimetic Therapeutics, Inc.

Title: Method for Periodontal Regeneration

Product Trade Name: GEM 21S® Growth-Factor Enhanced Matrix

Term Extended: 989 days

Expiration Date of Extension: March 8, 2012

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE By FAX: (571) 273-7755
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy RE: GEM 21S® Growth-Factor
Food and Drug Administration Enhanced Matrix
10903 New Hampshire Ave., Bldg. 51, Rm. 6222 FDA Docket No.: 2006E-0234
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

¹Subject to the provisions of 35 U.S.C. § 41(b).